

REMARKS/ARGUMENTS

Applicant notes with appreciation of the detail and thoroughness of the examination embodied in Paper No. 20080801 and the opportunity to distinguish the pending claims over the prior art of record.

Applicant incorporates by reference all remarks previously made of record. With this response, Applicant maintains that Mainwaring fails to teach an anaerobic polymerization chemical as required by subject claim 1. Applicant further maintains that one of ordinary skill in the art considering the Mainwaring reference and concerned with polymerization reactions that occur too fast would not be motivated to use the activators (e.g. copper octoate) which are taught by Boeder et al. to solve the problem of anaerobic reactions occurring too slowly; let alone for medical purposes on substrates involving no glass or metal. Additional deficiencies of Mainwaring and Boeder in light of the current claim amendments are presented *ante*.

Currently claim 1 is amended without prejudice or admission to recite that said package is peelable to expose the pre-moistened applicator while shielding the same from user contact. These amendments are made in the interest of furthering prosecution and not as means of limitation or relinquishment of stated or equivalent subject matter. This amendment is fully supported by the specification has filed *inter alia* page 6, lines 1-2. As such, no new matter is added by way of amendment.

With the outstanding office action claims 1-4, 6, 9, 12 and 13 stand rejected under 35 U.S.C. §102(e) as anticipated by Mainwaring et al. (U.S. Patent No. 6,779, 657).

Claims 14-16 are rejected under 35 U.S.C. §103(a) as unpatentable over Mainwaring et al. in view of Boeder (U.S. Patent No. 4,373,077).

Claim 5 stands rejected under U.S.C. §103(a) as unpatentable over Mainwaring et al. in view of Spinu et al. (U.S. Patent No. 5,210,108).

**Remarks directed to the rejection of claims 1-4, 6, 9, 12 and 13
under 35 U.S.C. §102(e) as anticipated by Mainwaring.**

Withdrawal of the rejection of claims 1-4, 6, 9, 12 and 13 as anticipated by Mainwaring is respectfully requested because Mainwaring fails to teach or suggest a package that is peelable to expose a pre-moistened applicator while shielding the same from user contact.

It is a tenet of patent law that anticipation has always been held to require absolute identity and process between the claimed process and a process disclosed in a single reference. In *Richardson v. Suzuki Motor Co., Ltd.*, 868 F.2d 1226, 9 USPQ2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The applicator of Mainwaring requires the presence of a handle such that the user can grasp an applicator and not have their hands contaminated with adhesive. (see col. 6, lines 50-53.) In contrast, the present invention envisions that the packaging shields the user from contact with an anaerobic polymerization reaction chemical, not a handle. Indeed, subject figures 1 and 2 illustrate that the orientation of the applicator tip 11A relative to the opening 19 is such that a user would only be protected by using the package casing 16 to shield himself from the contents of the package.

No identified teaching in Mainwaring involves the packaging serving as a protective surface. Each identified instance of Mainwaring involves a protective surface affixed to the

applicator and separate from any packaging such that using the packaging as a protective surface is not envisioned therein.

With regard to claim 3, the packaging of Mainwaring is not attached to the applicator therein. Mainwaring teaches that 16 and 18 are a portion of the cover that serve as a “retainer or a seal.” (see col. 6, line 64 to col. 7, line 1.) The purpose of these elements is not to affix the swab to the packaging, but instead to seal the passageway in the packaging so that the adhesive material cannot escape up the passageway and leak externally from the package. (See col. 7, lines 57-58.) The analogous portion of the instant invention is the breakable seal. (See Figs. 1A-C at 17; page 7, lines 10-18.) The use of Mainwaring 16 and 18 as merely a sealing means is found from the statement at col. 6, lines 26-30 that states: “the retainer 16 can also be a seal. The retainer 16 and the seal 18 may be partially or altogether replaced by particular technique employed to form the tray 10, such as shrink wrapping.”

Moreover, the swab and handle must be removable from the packaging in the invention of the Mainwaring. Mainwaring teaches “[t]he swab tip is then removed from the plunger using the swab handle so that the polymerizable adhesive material can be applied to a desired surface.” (col. 13, line 65 to col. 14, line 1.) (internal references omitted as this same sentence is repeated at col. 14, lines 64-67 with respect to another embodiment.) Overall, Mainwaring fails to teach or suggest that the applicator is attached to the package and not removable therefrom and that the package serves as a protective surface- an element incorporated into claim 3 from its dependency from claim 1. Thus, claim 3 has an independent basis of patentability.

In light of the forgoing amendments and remarks, claim 1 is believed to be in allowable form and directed to patentable subject matter. As claims 2-4, 6, 9, 12, and 13 each depend from claim 1, these claims are similarly submitted to be in allowable form and directed to patentable

subject matter. Reconsideration and withdrawal of the rejection of claims 1-4, 6, 9, 12, and 13 and passage of these claims to allowance is respectfully requested.

**Remarks directed to the rejection of claims 14-16 under 35 U.S.C. § 103(a) as being
unpatentable over Mainwaring in view of Boeder.**

Reconsideration and withdrawal of the rejection of claims 14-16 under 35 U.S.C. § 103(a) as unpatentable over Mainwaring in view of Boeder is respectfully requested as neither Mainwaring nor Boeder teach or suggest all elements of claim 1 from which claims 14-16 depend.

Standards for Obviousness Rejection and Response

The Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007), has recently articulated the standard for establishing whether a claim is obvious over prior art. In *KSR* the Court reestablished that *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), remains the controlling precedent. Under *Graham*, to establish a *prima facie* case of obviousness an Examiner must analyze:

- (1) the scope and content of the prior art;
- (2) the differences between the claimed invention and the prior art; and
- (3) the level of ordinary skill in the pertinent art.

Graham, 383 U.S. at 17–18, 148 USPQ at 467.

It is Applicant's understanding that the form and substance of rejections under 35 U.S.C. §103(a) are currently governed by guidelines articulated in the Federal Register, 2007, Vol. 72, No. 195, 56525-56534 therein embodying the test outlined in *KSR*. These guidelines require a

factual inquiry, resolution of ordinary skill in the art to which the invention pertains, and an explicit recitation of the rationale for the rejection as selected from among seven possible bases (identified in the Federal Register with letters A-G). The basis for Applicant's reply is also provided within the Federal Register guidelines.

While the outstanding rejection appears to address the scope and content of the prior art and the differences between the claimed invention and the prior art, the level of ordinary skill in the art is not articulated either expressly or inherently. As such, the outstanding rejection fails to satisfy all elements required for a finding of obvious as required under the analysis defined in *Graham* and reaffirmed in *KSR*. Applicant's remarks *infra* address each of the *Graham* elements and the rationale for a conclusion of obviousness.

Resolution of One of Ordinary Skill in the Art

Applying the examination guidelines for determining obviousness in view of *KSR International Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007) as found in the Fed. Register Volume 72(195) 57526-57535, the factual inquiry associated with determining obviousness under 35 U.S.C. §103 requires resolution of the level of ordinary skill in the art. The guidelines state with this regard:

Any obviousness rejection should include, either explicitly or implicitly in view of the prior art applied, an indication of the level of ordinary skill. A finding as to the level of ordinary skill may be used as a partial basis for a resolution of the issue of obviousness.

The person of ordinary skill in the art is a hypothetical person who is presumed to have known the relevant art at the time of the invention. Fed. Register Volume 72(195) at 57528.

“A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.” *KSR*, 127 S. Ct. at 1742. Within the outstanding Office Action it is respectfully requested that the level of ordinary skill in the art be stated with greater specificity as the present invention is submitted to require skills beyond those imparted to a single person of ordinary skill in the art. Upon identification of the level of ordinary skill in the art, Applicant reserves the right to make of record additional declarations provided under 37 CFR 1.132 detailing how particular claimed aspects are beyond the scope of various such professional individuals such as a chemist or molding compound manufacturer.

Rationale for Obviousness

The Supreme Court and the Court of Appeals for the Federal Circuit are in agreement that the teaching, suggestion, and motivation test as used by the CAFC is fully consistent with an analysis of obviousness under *Graham*. The Court in *KSR* articulated that “[t]here is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis,” and explained that the CAFC has, in many cases, applied the TSM test in accord with the principles of *Graham*. *KSR*, 127 S. Ct. at 1732, 82 USPQ2d at 1396. The Supreme Court also commented that the CAFC “no doubt has applied the test in accord with these principles [set forth in *KSR*] in many cases.” *Id.*

The CAFC has interpreted *KSR* to require an explicit showing that the prior art would have suggested making the specific modifications necessary to achieve the claimed invention. In *Ortho-McNeil Pharmaceutical, Inc. v. Mylan Laboratories, Inc.*, the CAFC continued application of the teaching, suggestion, and motivation test “flexibly applied” so as to require that any *prima facie* case of obviousness must be accompanied by an explicit showing where the

relied on prior art provided the requisite teaching, suggestion, or motivation. 520 F.3d 1358, 1364-65 (Fed. Cir. 2008). The flexible nature of the test allows for a teaching, suggestion, or motivation to arise from knowledge in the art or from a standard desire to improve on prior inventions. However, if the cited prior art is limited to patents and publications as it is in the subject rejection, and does not draw on additional sources such as general knowledge in the art, the teaching, suggestion, or motivation to modify that prior art must be found therein and this teaching, suggestion, or motivation must be made explicit. The prior art of record fails to provide, explicitly or inherently, any teaching, suggestion, or motivation that would lead a person having ordinary skill in the art to the instantly claimed invention.

The BPAI also recognized that *KSR* “held that the TSM test must be applied flexibly, and take into account a number of factors ‘in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed.’” *Ex parte Whalen II*, Appeal 2007-4423, July 23, 2008, page 15 (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007)). Further, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements in the way the claimed new invention does . . . To facilitate review, this analysis should be made explicit.” *Id.* Finally, in the face of evidence that a reference teaches away from the claimed invention the BPAI stated “it must be shown that those of ordinary skill in the art would have had some apparent reason to modify the known composition in a way that would result in the claimed composition.” *Ex parte Whalen II*, Appeal 2007-4423 at 16. Taken in sum, the BPAI recognizes that any *prima facie* case of obviousness must explicitly identify where any of multiple cited prior art provides motivation to combine the references so as to produce the claimed invention. This test is not met by the subject rejection in that the prior art of record fails to provide, explicitly or inherently, any

teaching, suggestion, or motivation to combine the references so as to lead a person having ordinary skill in the art to the instantly claimed invention.

The standard set down in *KSR* is fully in line with historical precedent. As supported by the CAFC, there must be an express evidentiary showing of where the prior art provides motivation to combine all elements of the claims. It is a well established legal principle that to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Additionally, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine reference teachings. *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). This suggestion or motivation must be made explicit.

In support of the above precedents, the Court in *KSR* suggested seven possible rationales for a finding of obviousness. These are captured in the Federal Register, 2007, Vol. 72, No. 195, 56525-56534, which serves as the current basis used by the USPTO for a finding of obviousness. These rationales are reproduced below.

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) “Obvious to try”—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one

based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

(Federal Register, Vol. 72, No. 195, 57529).

The basis of the rejection is "Mainwaring teaches every element of claims 14-16 except for the copper compounds." (Paper No. 20071220, page 4.) Boeder is cited as correcting the deficiency of Mainwaring with respect to claims 14-16. *Id.* at 4. Thus, "[i]t would have been obvious to one of ordinary skill in the art to combine the copper compounds from Boeder with the applicator assembly of Mainwaring." *Id.* at 5. The explanations articulated in Paper Nos. 20080801 and 20071220, lead Applicant to the assumption that the rationale for obviousness corresponds to rationale (A) of the *KSR* obviousness examination guidelines namely that the Examiner has found all elements in the cited prior art that may be combined according to known methods to yield predictable results. In the event that Applicant's assumption as to the rationale for the rejection is incorrect, it is respectfully requested that the undersigned attorney of record be contacted at the earliest possible convenience so that a response may be provided consistent with the implicit rationale for the finding of obviousness. The requirements for an obviousness rejection based on this rationale are reproduced below.

To reject a claim based on this rationale, Office personnel must resolve the *Graham* factual inquiries. Office personnel must then articulate the following:
(1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;

(2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately; a finding that one of ordinary skill in the art would have recognized that the results of the combination were predictable; and (4) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness.

Thus, to satisfy a *prima facie* case of obviousness under rational A, all elements must be found in the cited prior art.

Graham Factual Findings and the Differences Between the Claimed Invention and the Prior Art of Record.

A *prima facie* case of obviousness is not satisfied because Mainwaring fails to teach or suggest a package that is peelable to expose a pre-moistened applicator while shielding the same from user contact. Applicant incorporates by reference all remarks *supra* with respect to the deficiencies in the teachings of Mainwaring. As claims 14-16 each incorporate all elements of subject claim 1, Mainwaring fails to teach or suggest all elements of claims 14-16 for which this reference is cited.

Boeder is cited merely for teaching anaerobically curing polymer compositions including activator compounds comprised of copper and that the copper compounds are preferred when the polymerization is to occur on non-reactive metal or non-metal surfaces. (Paper No. 20071220, pages 4-5.) No cited teaching of Boeder bolsters the deficiencies of Mainwaring. The combination of Mainwaring and Boeder fails to teach or suggest a package that is peelable to

expose a pre-moistened applicator while shielding the same from user contact. As such, a *prima facie* case of obviousness is not satisfied under rationale A, the test outlined in *KSR*, or the historical precedent upon which *KSR* is based.

All claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The combined teachings of Mainwaring and Boeder fail to satisfy a *prima facie* case of obviousness under rational A or the relevant case law. In light of the foregoing amendments and remarks it is respectfully requested that the rejection of claims 14-16 be withdrawn.

**Remarks directed to the rejection of claim 5 under 35 U.S.C. § 103(a) as being
unpatentable over Mainwaring in view of Spinu.**

Reconsideration and withdrawal of the rejection of claim 5 under 35 U.S.C. § 103(a) as unpatentable over Mainwaring in view of Spinu is respectfully requested as neither Mainwaring nor Spinu teach or suggest all elements of claim 1 from which claim 5 depends.

Applicant incorporates by reference the remarks *supra* that Mainwaring fails to teach or suggest all elements of claim 1. Spinu is cited as teaching a lanthanide compound for use in a polymerization process. (Paper No. 20071220, page 5.) No cited teaching of Spinu bolsters the aforementioned deficiencies of Mainwaring. As such, the combination of Mainwaring and Spinu fails to teach or suggest all elements of claim 5 as required for a *prima facie* case of obviousness under rationale A.

In light of the foregoing amendments and remarks, Applicant respectfully requests that the rejection of claim 5 under 35 U.S.C. §103(a) be withdrawn.

Summary

Entry of this amendment is respectfully requested. Each of the pending claims is believed to be in allowable form and directed to patentable subject matter. Reconsideration and withdrawal of the rejections is solicited. Should the Examiner have any suggestions as to how to improve the form of the pending claims, he is respectfully requested to contact the undersigned attorney in charge of this application.

Respectfully submitted,

Date: December 22, 2008

Electronic Signature: /Avery N. Goldstein/
Avery N. Goldstein, Ph.D.
Registration No. 39,204
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, P.C.
P.O. Box 7021
Troy, MI 48007-7021
(248) 647-6000

Attorney for Applicant